K061134

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

EFS Eberle Feinwerktechnische Systeme GmbH & CO. KG
Shaver System

SEP - 1 2006

April 17th, 2006

1. Submitter Information:

a. Correspondent/ Distributor:

Name:	Innovative Endoscopy Components, LLC
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Fax:	(954) 217-8781
E-Mail:	info@endoscopy.md
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Owner/ Operator No:	9026517

b. Manufacturer:

Name:	EFS Eberle Feinwerktechnische Systeme GmbH & CO. KG
Address:	Glasbronnenstrasse 6 D-75449 Wurmberg GERMANY
Telephone:	(+49) 07044-9611-0
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E-Mail:	info@efs-eberle.de
Registration No:	_____
Owner/ Operator No:	_____

2. Device Name:

Classification Name:	Arthroscope and Accessories
Common Name:	Surgical Shaver and Accessories
Proprietary Name:	EBERLE Shaver System C2 and Shaver Blades

3. Classification

Classification Number:	CFR 888.1100 Class II
Product Code:	HRX

4. Indication for use:

The EBERLE Shaver System C2 is a powered instrument system and consists of a control unit, a footswitch, a handpiece and accessories. It is designed for arthroscopy surgical procedures like shaving, burring, abrading, cutting and resecting of fibrous tissue, cartilage tissue and bone conducted by qualified surgeons only.

5. Description of Device:

The EBERLE Shaver System is a powered surgical instrument system and consists of a control unit, a footswitch, a handpiece and associated shaver blades (autoclave-reusable, sterile/ non-sterile).
All these components are designed, constructed and intended to be operated exclusively as a unit.

6. Substantial Equivalence:

K973195, Stryker Total Performance System Shaver
K030009, KSEA Powershaver System S2
K990524, Linvatec E9000 System
K002523, Linvatec Advantage Drive System

7. Description of Safety:

The selection of the materials for the EBERLE Shaver System C2 and Blades has been determined through demonstrated appropriate levels of biocompatibility. The materials are similar or identical to those used for predicate devices as well as other brands legally sold in the United States.

8. Summary:

Biocompatibility, function, indications and designs have been developed to ensure the safety of this device and it is substantially equivalent to commercially approved shaver systems available for sale in the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

EFS Eberle Feinwerktechnische System
% Innovative Endoscopy Components, LLC
Mr. Florian Gruber
1112 Weston Road, PMB 227
Ft. Lauderdale, Florida 33326

SEP - 1 2006

Re: K061134
Trade/Device Name: EBERLE Shaver System C2 and Shaver Blades
Regulation Number: 21 CFR 888.1100
Regulation Name: Athroscope
Regulatory Class: II
Product Code: HRX
Dated: July 28, 2006
Received: August 1, 2006

Dear Mr. Gruber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061134

Device Name: EBERLE Shaver System C2 and Shaver Blades

Indications For Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K061134